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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,140	04/12/2004	Kevin Gardner	31978-202807	1168

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EXAMINER	
SKIBINSKY, ANNA	
ART UNIT	PAPER NUMBER
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,140	GARDNER ET AL.	
	Examiner	Art Unit	
	Anna Skibinsky	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *97 and 100-119* is/are pending in the application.

4a) Of the above claim(s) *113-115,117 and 118* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *97,110-112,116 and 119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Amendments

Claim 97 has been amended and claim 119 is newly introduced. Claims 97, 100-112, 116 and 119 are currently under examination.

Claim Election/Restriction

The restriction was made Final in the Office action filed 8/11/2006 and ~~further arguments and~~ further traversal arguments are not germane to prosecution.

Claim Rejections - 35 USC § 112-2nd paragraph

The rejection of claim(s) 97, 100-112 and 116 for being Vague and Indefinite under 35 USC § 112-2nd paragraph in the Office Action filed 8/11/2006 is withdrawn in view of Applicant's Remarks/Amendments filed 11/13/2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 97, 100-112, and 116 are rejected under 35 U.S.C. 102(e) as being anticipated by Watt et al (US Patent No.: 6,994,982, filed May 5, 2000).

2. Claim 97, step (1), and claim 119, recites a kit comprising recombinant constructs each having an expression control sequence from a gene of a coordinated system of interest, operatively linked to a sequence encoding a reporter.

3. Watt et al. teach a first nucleotide sequence that encodes a reporter molecule and a second nucleotide sequence from a known genomic sequence that encodes the amino acid sequence that promotes expression (col. 11, lines 47-56). The first sequence is operably under the control of a biological activity encoded for by the second sequence (col. 10, lines 30-54; col. 20, lines 57-67; col. 25, line 62 to col. 26, lines 2; and throughout the text). The nucleotide sequences are taught as being a plurality (col. 10, lines 55-62) of recombinant constructs (col. 31, lines 38-61)

4. Claim 97, step (2), recites at least three agents from a first set of agents that are known or predicted to act on one of the expression control sequences.

5. Watt et al. teach a variety of different agents that modulates biological activity and target protein: DNA, peptide:DNA, or peptide:protein interactions. The agents can be antigens, antibiotics, or inhibitory agents (col. 7, line 64 to col. 8, line 21). A list of diverse categories of agents is provided (col. 1, line 50 to col. 2, line 12).

6. Claim 97, step (3) recites about three agents from a second set of agents wherein the agents from the first and second sets of agents are combined in an inter-set combinatorial fashion.

7. Watt et al. teach agents which are candidate compounds such as a small molecule, drug, antibiotic or other compound which, when combined with a carrier molecule can be taken up by a cell (col. 18, lines 1-6 and lines 25-32). The method disclosed herein includes inhibitory agents that target specific amino acid: amino acid or amino acid:nucleic acid sequence interactions (col. 18, lines 25-32).

8. Claims 100 and 101 recite expression control sequences from genes involved in signal transduction, apoptosis, or cell growth.

9. Watt et al. teach cell death, cell growth and signal transduction as a result of introduction of an amino acid sequence that acts as an agent which impacts the expression of the reporter molecule (col. 30, lines 31-35 and lines 53-63; and col.32, lines 3-9).

10. Claim 102 recites the number of control sequences linked to reporter sequences is at least about 8.

11. Watt et al. teach using fragments of genomes on the order of molar amounts (col. 13, liens 29-34).

12. Claim 103 recites a reporter sequences encoding green fluorescent protein, luciferase or beta-galactosidase.

13. Watt et al. teach reporter genes which express luciferase or beta-galactosidase (col. 11, lines 47-56) and green fluorescent protein (col. 28, line 51 to col. 52, line 4).

14. Claim 104 recites wherein three agents in the first set of agents and three agents in the second set are different are chemical compounds, biological agents, drugs, drug candidates, toxins, antibodies, transcription inhibitors or combinations thereof.

15. Watt et al. teach an example wherein one set of agents that affect cell growth or viability and are toxins, a cytostatic compound or anti-mitotic compound (col. 29, line 64 to col. 30, line 2). Anther set of agents, different from the first set are taught as being antifungal agents, isotonic agents and agents delaying absorption (col. 31, line 62 to col. 36, line 23). These agents are those that modulate the biological activity linked with the expression of the sequences (col. 35, lines 29-55).

16. Claim 105 recites at least about three agents in the first set represent different categories of stimuli for a cell than the about three agents in the second set, wherein the agents in the two sets are:

a) agents that act at the surface of a cell vs. agents that function within a cell, and/or

b) agents that exhibit different mechanisms of action.

17. Watt et al. teach agents that target the cell wall or a membrane transport component (col. 8, lines 17-21) or agents that target peptide:peptide, protein:protein or protein:DNA interactions which are interactions found inside a cell.

18. Claim 106 recites agents form a first and/or second set which induce one or more of the following responses when introduced to or into cells:

a) altered levels of RNA production in response to the agent.

19. Watt et al. teaches RNA replication which is effected by agents which target biological interaction or activity (col. 1, line 50 to col. 2, line 3).

20. Claim 107 recites agents in the first set which are mitogens.

21. Watt et al. teaches the introduction of mitogens into the cell (col. 30, lines 31-35).

22. Claim 108 recites agents in the second set are pharmaceuticals.

23. Watt et al. teaches agents which are drugs or antibiotics (col. 18, line 1-6).

24. Claim 109 recites the limitations of claims 107 and 108 above.

25. Claim 110 recites at least tow of the first set of agents are combined in an inter-set combinatorial fashion.

26. Watt et al. teach combining agents with solvent or a dispersion medium containing agents such as water, PEG, ethanol or combining agents with a coating such as lecithin (col. 36, lines 8-15).

27. Claim 111 recites a first set of at least about 6 agents and a second set containing at least about 8 agents.

28. Watt et al. teach caring out processes with indicate concentrations on the level of molarities of agents (col. 13, lines 28-34; and col. 36, lines 8-15).

29. Claim 112 recites a first set of at least about 6 agents and the second set of at least about 8 agents.

30. Watt et al. teach caring out processes with indicate concentrations on the level of molarities of agents (col. 13, lines 28-34; and col. 36, lines 8-15) which include an exponential number of agents.

31. Claim 116 recites three agents from a third set of agents which are different from the agents in the first and second set.

32. Watt et al. teaches agents that are antifungal such as parabens, chlorobutanols, phenol, phenol, isotonic agents such as sugars, or sodium chloride, and agents delaying absorption such as aluminum monostearate and gelatin (col. 36, lines 15-20).

RESPONSE TO ARGUMENTS

33. Applicant's arguments filed 11/13/2006 have been fully considered but they are not persuasive.

34. Applicants argue that Segal et al. do not disclose an assay or a kit (Remarks, page 10, lines 7-8).

35. In response, Segal et al. teach a process and the components to carry out the process. The specification of the instant application does not provide a specific definition of a kit or limit the recited kit to a specific package of components. The prior art of Segal et al. teaches all the elements of the claimed kit and the use of those elements and thus anticipates the claimed invention. Furthermore, examples of specific physical components used in the method of the prior art are taught (see Examples 1-5).

36. Applicants argue that Segal et al. do not teach a "coordinated system of interest" (Remarks, page 10, lines 9-10).

37. In response it is noted that neither the instant claims nor the specification provide a definition for a "coordinated system of interest". The term "coordinated system of interest" is open to embodiments presented in the prior art because "coordinated system" can be construed as that taught by Segal et al., a system that is being studied (i.e. "as system of interest") and the its components ("coordinated"). Thus, the teaching of Segal et al. can be construed as "a coordinated system of interest" and the claims are not distinguished over the prior art.

38. Applicants argue that Segal et al. teach putative mediators or modulators and do not teach the recited "expression control sequences" (Remarks, page 11, lines 14-19).

39. In response, mediator or modulators effect or control expression of genes and thus reads on the limitation of "expression control sequences." A definition in the specification or a limitation that excludes these embodiments for "expression control sequences" is not provided. Thus, the claim recitation of "expression control sequences" reads on the prior art because Segal et al. teach sequences which can effect or control expression of genes. As reiterated in the above rejection, Segal et al. teaches amino acid sequences promote expression (col. 11, lines 47-56). The first sequence is operably under the control of a biological activity encoded for by the second sequence (col. 10, lines 30-54; col. 20, lines 57-67; col. 25, line 62 to col. 26, lines 2; and throughout the text). The nucleotide sequences are taught as being a plurality (col. 10, lines 55-62) of recombinant constructs (col. 31, lines 38-61)

40. Applicants argue Segal et al. does not teach the newly added claim 119, dependent from claim 97, which recites "at least 5 recombinant constructs, each of which comprises an expression control sequence ..." (Remarks, page 11, lines 24-27).

41. Applicants argue a limitation not recited in the claim. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 119, only recites "a kit of claim 97, which

comprises at least 5 recombinant constructs," with no indication that the recombinant constructs of claim 119 are the same as those in claim 97 which comprise an expression control sequence. In Segal et al., the nucleotide sequences are taught as being a plurality (col. 10, lines 55-62) of recombinant constructs (col. 31, lines 38-61), as pointed to in the above rejection.

42. Applicants argue (Remarks, page 12, lines 1-16) that the prior art of Segal et al. do not teach agents from the first group and agents from the second group that "are combined in an inter-set combinatorial fashion", as recited in the limitations of claim 97, step (3). Applicants point to the specification for a preferred embodiment of "inter-set combinatorial fashion."

43. In response, the claim 97 currently does not recite what the agents from the first and second group are combined with. The prior art of Segal et al. teaches the combining of different molecules such as a drug, antibiotic or other compound with a carrier molecule that can be taken up by a cell (col. 18, lines 1-6 and lines 25-32). The method disclosed herein includes inhibitory agents that target specific amino acid: amino acid or amino acid: nucleic acid sequence interactions (col. 18, lines 25-32). The limitation of the instant claim encompasses the teaching of Segal et al. in that one group or agents are combined with another group of agents such that agents "are exposed to each member of a plurality of biological entities in an inter-set combinatorial fashion," (specification page 14, lines 6-8). The specification does not provide a limiting definition for "inter-set combinatorial fashion" and thus, "inter-set combinatorial fashion" recited in

the claim 97 is open to the interpretation of combining one set of biological agents with another set of biological agents.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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